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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,506	12/21/2001	Hanuman B. Jampani	ETH-1601 (J&J 3.0-071)	4582
27614	7590	06/06/2005	EXAMINER	
MCCARTER & ENGLISH, LLP FOUR GATEWAY CENTER 100 MULBERRY STREET NEWARK, NJ 07102			FUBARA, BLESSING M	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/029,506

Applicant(s)

JAMPANI ET AL.

Examiner

Blessing M. Fubara

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 and 27-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 and 27-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of request for continued examination, amendment and remarks filed 04/25/2005. Claims 1-25 and 27-45 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 04/25/05 has been entered.

NEW MATTER

Claim Rejections - 35 USC § 112

2. Claims 1-25 and 27-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite “mass”, “hollow”, “exterior walls”, “planar”, “walls” and “exterior”, which are not support by the description of the invention as filed (see in re Wright, 866 F.2d 422, 9 USPQ2d 1649 (Fed. Cir. 1989).

Claim Rejections - 35 USC § 102

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Art Unit: 1618

4. Claims 1-10, 17-24, 27-33 and 39-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosenthal et al. (EP 0 562 864).

Rosenthal discloses a wound dressing material or implant material that comprises a matrix of bioabsorbable biopolymer material and substructure of bioabsorbable biopolymer films embedded in the matrix structure; one or more active agents are incorporated separately into the matrix and/or the substructure in order to provide controlled or phasic release of the active agent into the wounds (abstract and column 3, lines 22-34).

Rosenthal teaches that polyglycolic acid, structural proteins such as collagen, elastin and fibronectin and polysaccharides are bioabsorbable materials that are used to fabricate the porous wound dressing or implants (column 1, lines 6-22). Anti-microbial agent is an example of active agent incorporated to control infection in the heteromorphic wound dressing sponge of Rosenthal (column 3, lines 36 and 37). In example 3, a two-component heteromorphic sponge wound dressing comprising chlorhexidine gluconate in both the sponge matrix and the substructure is prepared and in this case, a variation of the preparatory method calls for the use of oxidized regenerated cellulose fabric pre-coated with hyaluronic acid (column 7, line 56 to column 8 line 6).

In Rosenthal, the substructure of polyglycolic acid film is the enclosing film and since the anionic carrier of oxidized regenerated cellulose interacts with the active anti-microbial agent that satisfies the limitation of cationic agent, the interaction would inherently be ionic. The instant method is directed to administering a pharmaceutical active agent and the reference applies the wound dressing sponge to a wound and the rate would inherently depend on the rate of biodegradability of the substructure. A sponge is a hollow structure having pores that define

Art Unit: 1618

the hollow-nature of the sponge. Since the polyglycolic acid film and heteromorphic sponge of Rosenthal occupy space, the film or the sponge can be regarded as a mass.

A sponge is porous and being a porous structure, the sponge broadly has exterior and interior walls, so that, although the exterior and interior walls now recited by the amended claims do not have support in the as filed description of the instant invention, the sponge broadly contains the limitations. Since the substructure of polyglycolic acid is the enclosing film and contains the active agent, the polyglycolic enclosing film is the envelope of the instant claims.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 11-16, 25 and 34-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenthal et al. (EP 0 562 864) in view of Suzuki et al. (JP 405163424) or Delgado et al. (US 5,614,310).

Rosenthal clearly teaches the porous biocompatible device of the instant invention where polyglycolic acid is an enclosing film. Rosenthal does not disclose polypropylene or polyethylene as the material for the enclosing film. It is known in the art that polyglycolic acid and propylene are all thermoplastic polymer materials (see English abstract of Suzuki, cited in prior office action). Therefore then, one thermoplastic material can be substituted for by another thermoplastic material without negative effect to the function device that contains the thermoplastic material. Regarding the size of the pores recited in the instant claims, it is noted that there is no demonstration in the as filed description of the invention that the recited pore sizes provides unusual results to the delivery device and the recited pore size would not convey

Art Unit: 1618

patentable distinction absent a showing. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a porous wound dressing sponge according to the teaching of Rosenthal where the enclosing film in polyglycolic acid. One having ordinary skill in the art would have been motivated to prepare the porous wound dressing sponge of Rosenthal and use polypropylene polymer film in place of polyglycolic acid since both polymers are thermoplastic and with the expectation that the device would function as well as the wound dressing sponge prepared with polyglycolic acid enclosing film.

Delgado also discloses a wound dressing that has polymeric film of polypropylene or polyethylene or polyvinyl chloride or polyester or polyurethane (column 3, lines 25-28) enclosing antimicrobial agent such as chlorhexidine gluconate (column 8, line 67). Since chlorhexidine gluconate can be enclosed by a polyglycolic film as in Rosenthal or the chlorhexidine gluconate can be enclosed by polypropylene or polyethylene or polyvinyl chloride or polyester or polyurethane as in Delgado for wound dressing in both references, one polymeric film can be substituted for another to form a wound dressing. The idea of combining Rosenthal and Delgado flows from *in re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

The combination of Suzuki and Rosenthal or Delgado and Rosenthal renders the designated claims obvious and Examiner agrees with applicants that the combination does not anticipate the designated claims.

Claim 40 and 41 contain new matter and the rejection is applied to claims 40 and 41 because the sponge of Rosenthal anticipates these claims. The same is true for claims 42 and

Art Unit: 1618

43. Rosenthal in view of Suzuki or Delgado renders claims 11 and 12 obvious as discussed above under 35 USC 103.

7. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
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Tech. Center 1600

